

### REMARKS

The rejection of claims 4, 11, 34, 37, 38 and 41 under 35 USC 103(a) as being unpatentable over Sharma (WO 92/19285) in view of Kokai (Japanese Patent Abstract No. 53-104724 - IDS-4) and Cloyd, et al (U.S. Patent No. 6,074,646) is respectfully traversed.

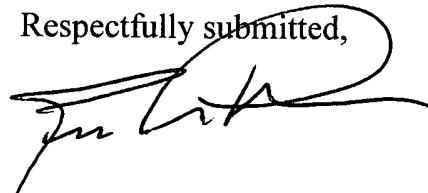
Applicant has amended the independent claims 11, 37 and 41 to identify the method as a method for detecting a hepatitis C virus or hepatitis B virus in a sample in which the sample is subjected to an immunoassay using the probe antibody in the presence of a treatment solution containing the components (a) and (b) or (a), (b) and (c) in which the presence of components (b) or components (b) and (c) reduces the denaturing effect of the anionic surfactant (a) to the probe antibody. The Examiner on page 5, paragraph 9 of the official action has specifically indicated to applicant that the claims were drawn to a method of "treating a hepatitis C (HCV)....." etc. and that the effects of the combined components of (b) and (c) for reducing adverse effects is not a limitation of the claims of record. In response to the Examiner's remarks, applicant has amended the claims so that it is clear that the method is a method for detecting a hepatitis C virus (HCV) or a hepatitis B virus (HBV) in a sample and not for treating a hepatitis C or B virus and that the "adverse effects" feature is now specifically included as a limitation of the claim. Since the Examiner admits that Sharma does not disclose the use of the claimed combination of surfactants and that neither Kokai (53-104724) or Cloyd, et al ('646) teach or recognize the ability to reduce the denaturing effect of an anionic surfactant (a) to the probe antibody using the combination of an amphoteric surfactant (b) and an agent (c), the arguments of the Examiner no longer have any validity. This recognition of reducing the denaturing effect is sufficient of itself to support patentability of the claims 11, 37 and 41 as now amended over the references of record.

Claims 4, 12, 34 and 38 are dependent claims and are therefore believed patentable for the same reasons given above with regard to claims 11, 37 and 41.

In view of the fact that this is a final rejection and that applicants' amended claims are being presented on the last day of the period for response, applicant is filing herewith a Request for Continued Examination (RCE) application to make of record these changes to the claims and to expedite and facilitate an allowance of the application as soon as conveniently possible.

Reconsideration and allowance of claims 4, 11, 12, 34, 37, 38 and 41 is respectfully solicited.

Respectfully submitted,



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#### MAILING CERTIFICATE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 attention MAIL STOP PATENT APPLICATIONS (RCE) with Express Mail Label no. EU483331573US on July 9, 2003.



Date: July 9, 2003

## AMENDMENT TO THE CLAIMS

**Claims 1-3, 5-10, 13-33, 35, 36, 39 and 40 (Cancelled)**

**Claim 4. (Previously Amended)** The method according to claim 31, wherein said treatment solution further contains urea, an imidazole ring-containing compound or an indole ring-containing compound.

**Claim 11. (Currently Amended)** A method for ~~treating~~ detecting a hepatitis C virus (HCV) or hepatitis B virus (HBV) ~~containing in a sample to obtain by obtaining a sample~~ suitable for detection of virus by a probe antibody, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution containing (a) an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant and a protein denaturant; ~~and wherein the denaturing effect of the anionic surfactant (a) to the probe antibody is reduced by the agent (b);~~

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated; ~~and~~

(3) subjecting the sample ~~and which sample is readily subjected to~~ an immunoassay using ~~a~~ the probe antibody in the presence of treatment solution.

**Claim 12. (Withdrawn)**

**Claim 34. (Previously Amended)** The method according to claim 32, wherein said treatment solution further contains urea.

**Claim 37. (Currently Amended)** A method for ~~treating~~ detecting a hepatitis C virus (HCV) ~~and or~~ a hepatitis B virus (HBV) ~~containing in a sample to obtain~~ by obtaining a sample suitable for detection of virus by a probe antibody, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphoteric surfactant, and (c) an agent selected from the group consisting of a nonionic surfactant and a protein denaturant; ~~and~~ wherein the denaturing effect of the anionic surfactant (a) to the probe antibody is reduced by the amphoteric surfactant (b) and the agent (c);

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and

~~(3) which~~ subjecting the sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

**Claim 38. (Previously Amended)** The method according to claim 33, wherein said treatment solution further contains urea.

**Claim 41. (Currently Amended)** A method for ~~treating~~ detecting a hepatitis C virus (HCV) ~~and or~~ hepatitis B virus (HBV) ~~containing in a sample to obtain~~ by obtaining a sample suitable for detection of virus by a probe, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphoteric surfactant, (c) a nonionic surfactant and (d) a protein denaturant; ~~and~~ wherein the denaturing effect of the anionic surfactant (a) to the probe antibody is reduced by the amphoteric surfactant (b), the nonionic surfactant (c) and the protein denaturant (d);

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and

          (3) which ~~subjecting the sample is readily subjected~~ to an immunoassay using a probe antibody in the presence of treatment solution.